up between the DEFENDANTS' AWP listing in the 1998 *Drug Topics* Red Book and Ven-A-Care's true 1998 wholesale cost for a common size.

134. <u>Defendants' Inflated Reports Of Prices And Costs Unlawfully Induce The Utilization Of The Specified Drugs</u>. The DEFENDANTS benefit directly from their false pricing scheme of concealing their true prices while making grossly inflated false and fraudulent representations of prices and costs by maximizing their products' sales volume, capturing market share for their products, and increasing utilization of their products by Providers. An example of how the DEFENDANTS directly benefit from their false pricing scheme is shown by data for the first quarter of 1997 from the State of Florida's Medicaid Program setting out Florida Medicaid's reimbursements paid to the customers of drug manufacturers and utilization of their products by their customers for the drug manufacturers and utilization of their products by their customers for the drug

135. The chart below sets out the number of reimbursed claims, VEN-A-CARE's cost per ml and "the Spread" between Medicaid reimbursement and true cost. A review of the chart clearly demonstrates that the vast majority of Providers utilize the manufacturer's drug with the greatest spread between the true Wholesale Acquisition Cost and the inflated false Wholesale Acquisition Cost reported by the drug manufacturer.

FL		PRICING SCHEI CAID REIMBUR		· · · · · · · · · · · · · · · · · · ·	г 1997)
Manufacturer	VAC's Cost per ml	Florida Medicaid Reimbursement per ml	The Spread	# of claims	Reimbursement paid by Florida Medicaid
	\$0.1065	\$0.3590	\$0.2525	12,673	\$763,595.42
	\$0.1125	\$0.3531	\$0.2406	9,792	\$707,220.50
	N/A	\$0.2138	**	102	\$4,981.86
	N/A	\$0.1787	**	19	\$1,278.08

TOTAL REIMBURSEMENT BY THE STATE OF FLORIDA	\$1,477,075.86
MEDICAID PROGRAM (January 1 through March 31, 1997)	

The use of the spread to falsify claims is evidenced by the fact that customers will receive a greater windfall by purchasing their product than they could if they somehow acquired the same product from free of charge.

drugs covered by Medicare, as evidenced by the history of the the brand name of which is and a generic equivalent was not available until 1997.

DEFENDANT brought the new drug onto the market in 1998, however, it falsely represented that the generic price was equivalent to the brand when it was substantially less. The following chart reveals the spread created by the false price

representations of the generic manufacturers, including , and the corresponding increase in Medicare utilization.

MEDICARE UTILIZATION FOR THE

YEAR	MEDICARE REIMBURSEMENT AMOUNT PER UNIT*	VAC COST PER MEDICARE UNIT**	"SPREAD" (PROFIT) \$	"SPREAD" (PROFIT) %	MEDICARE EXPENDITURES
1995	\$ 3.11 mg. (\$0.62/ml)	\$3.11	\$0.00	0%	\$14,426,108
1996	\$ 3.75 mg. (\$0.75/ml)	\$3.26	\$0.49	15%	\$47,388,622
1997	\$ 3.50 mg. (\$0.70/ml)	\$2.15	\$1.35	63%	\$96,204,639
1998	\$ 3.34 mg.	\$1.70	\$1.64	96%	\$176,887,868
1999	\$ 3.34 mg.	\$1.60	\$1.74	108%	\$253,400,414
2000	\$3.34 mg.	\$0.94	\$2.40	255%	\$347,527,960
2001	\$4.34 mg.	\$0.82	\$2.52	307%	

Medicare Units were converted from ml's to mg's for the years 1995,1996 &1997. (5 ml=1 milligram) and 1998-2001 @95% of AWP

137. Defendants' False Price Scheme Causes Over-Utilization Of Particular

<u>Drugs</u>. The grossly inflated payments unwittingly made by Medicare/Medicaid not only served as an inducement to Providers to purchase a particular manufacturer's product but also served to drive over-utilization. The Relator, prior to filing the initial Complaint in this

^{**} VAC's cost were obtained from McKesson Drug Company published wholesale prices and do not include any common industry discounts or incentives or prices obtained through a group purchasing organization ("GPO").

action, surveyed three national pharmacy Providers of to determine their business practices for their sales of to the Medicare and State Medicaid Programs. The Relator's principals used positions in an affiliated home health care company to pose as an interested customer. The Relator determined that the payment of kickbacks and/or split fees were commonplace between the pharmacies and home health care companies who could provide the pharmacies with patient referrals. One marketing scheme offered by one of the pharmacies was the automatic shipping of refills of every month without verifying continuing need with the patient or physician in order to maximize the sales of the automatic shipping and reimbursement.

- That The Medicare Patient's 20% Co-Payment Exceeded The Cost Of The Drug To The Provider. For many of the specified drugs, the DEFENDANTS' false representations of price and cost caused the Medicare Program to pay and approve claims at such exorbitant amounts that the 20% co-payment paid by the patient exceeded the true price of the drugs. In such instances, Medicare patients were in effect being entirely denied the prescription drug benefit to which they were legally entitled under Medicare. Exhibit 3 hereto provides examples of such drugs.
- 139. <u>Defendants' Inflated Price Reports Cause Some Generic Drugs To Be</u>

 <u>More Expensive Than The Brand Drug</u>. In many cases the DEFENDANTS' false claims scheme has caused the Government to pay claims for generic equivalents in amounts greater than the claims that would have been paid for the brand name version of the drug. The DEFENDANTS have thus deprived the Government of the expected savings arising

from utilization of generics. Exhibit 4 attached hereto sets forth examples of such instances.

- 140. The Government Loses The Benefit Of Normal Price Competition. The DEFENDANTS' false claims scheme has also deprived the Government of the benefits of normal price competition causing it in some cases to pay over one thousand percent above the price that would be set by normal market forces, but for the DEFENDANTS' false price and cost representations.
- 141. Reported Prices On Drugs Sometimes Rose While Actual Prices Stayed

 Constant Or Decreased. The Government and its health program beneficiaries are

 damaged when the DEFENDANTS create a financial inducement for Providers to order

 drugs by continually increasing the spread over time.

amounts being paid to their customers by the Medicare and State Medicaid Programs for claims submitted for the specified drugs. The exorbitant payments induce physicians, clinics and pharmacies to increase utilization of the specified drugs. The financial inducement was so great for many of the specified drugs that the profits derived from the provision of the specified drugs greatly exceeded the physicians' professional fees and provided what can only be characterized as "windfall profits." Over the last six (6) years, the Relator's business has all but been extinguished because of the Relator's refusal to benefit from the false and fraudulent claims schemes specified herein. The Relator has been unable to effectively compete with those physicians, clinics and pharmacies who benefit from the DEFENDANTS' false claims scheme because the financial inducement to the prescribing physicians often exceeds their compensation from the practice of medicine.

143. The Dollar Amount Of The Financial Inducement To Providers From The False Price Scheme Can Be Enormous. The financial inducement to those in a position to increase the utilization of the DEFENDANTS' drugs is illustrated by the examples of common drug therapies using certain of the specified drugs contained in Exhibit 5 hereto.

144. <u>Illegal Profit Spreads Are Often Enhanced By Additional Unlawful</u>
Financial Inducements Such As Free Goods, Direct Monetary Payments, Rebates,

And Agreements To Falsify Invoices. The DEFENDANTS further act to increase the illegal profit spread, over and above that resulting from their false price and cost reports, through additional unlawful financial inducements which are concealed from the Government such as:

- a) Providing or arranging for the delivery of free goods in exchange for the purchase of the DEFENDANTS' specified drugs, the value of which is concealed from the Government, resulting in an additional spread between the true acquisition cost of the specified drugs and the false prices upon which Medicare and Medicaid reimburse.
- b) Making direct monetary payments to the Provider ordering the drugs and concealing the true purpose of the payment by classifying it as a "marketing grant", "educational grant", "administrative fee", "research grant" or other name when the payment is, in truth, a financial inducement for ordering the drugs.
- c) Paying rebates to the Providers which are concealed from the Government.
- d) Falsifying invoice prices to conceal additional reductions in the Provider's true acquisition cost of the drugs.
- 145. Each of the methods employed by the DEFENDANTS in paying illegal financial inducements has the effect of misleading the Medicare and Medicaid Programs about the Providers' cost of the drugs and of impeding the Programs' ability to estimate acquisition costs. The DEFENDANTS' actions result in claims being paid at exorbitant amounts.

SECTION NO. 9

THE DEFENDANT DRUG MANUFACTURERS' KNOWLEDGE OF THE FALSE CLAIMS SCHEME

- 146. The DEFENDANTS are prohibited by the False Claims Act from making false representations in connection with claims for Government funds, are required by the Food and Drug Act to report true prices and are prohibited by the Medicare and Medicaid Anti-Kickback laws from arranging financial inducements for Providers.
- 147. The patients and third party payers, including the Medicare and State Medicaid Programs, are not aware of the prices actually paid for the specified drugs by the physician, clinic or pharmacy presenting the claim for payment. The DEFENDANTS concealed from the Medicare and State Medicaid Programs price reductions occurring due to competition in the marketplace and falsely and fraudulently represented drug prices that far exceeded the truthful prices.
- 148. At all times material to this action, each of the DEFENDANTS acted "knowingly" as that term is defined at 31 U.S.C. §3729(b) by, among other things:
- a) Causing the presentation of false and fraudulent claims for payment or approval by the Medicare and States Medicaid programs; and
- b) Making and using false statements and/or records for the purpose of getting false or fraudulent claims approved or paid by the Medicare and State Medicaid Programs.
- 149. The DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that their conduct would cause

Medicare/Medicaid to pay claims for the specified drugs in amounts exceeding that contemplated by applicable law, in part, because:

- (a) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that Medicaid was required to pay claims based upon the drugs' Estimated Acquisition Cost ("EAC") to the Provider submitting the claim. 42 C.F.R. §447.331.
- (b) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that federal statutes and regulations limited payment of Medicaid claims for the specified drugs to a reasonable estimation of the acquisition cost.
- (c) Each of the DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that federal statutes and regulations limit payment of Medicare Part B claims for the specified drugs to 80% of a reasonable cost, one that reflects the true cost of the drug. See 42 C.F.R. 405.517.
- (d) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that neither Medicare nor Medicaid was authorized or permitted by applicable law to pay claims for the specified drugs in excessive amounts.
- (e) Each DEFENDANT DRUG MANUFACTURER knew or recklessly disregarded or acted in deliberate ignorance of the fact that the State Medicaid Programs contracted through their fiscal agents with First Databank and Medi-Span to obtain the DEFENDANT's reported prices and costs and used the prices from First Databank and

Medi-Span to establish the estimated acquisition cost for the specified drugs for reimbursement purposes.

- (f) Each DEFENDANT knew or recklessly disregarded or acted in deliberate ignorance of the fact that Medicare, through its Carriers and DMERCs, utilized DEFENDANTS' reported AWP prices as contained in Red Book, to establish its reimbursement amounts for the specified drugs.
- (g) Each of the DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that the State Medicaid Programs utilized DEFENDANT'S reported prices and costs to calculate the Estimated Acquisition Cost.
- (h) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that they were supplying to First DataBank, Red Book and Medi-Span, prices and costs which these reporting compendia reported to Medicare and/or Medicaid and that these compendia relied solely on DEFENDANTS to obtain its prices.
- (i) The DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that they required wholesalers to report back to DEFENDANTS, and that wholesalers did in fact routinely report back to the DEFENDANTS, all prescription drug sales by NDC number, provider name and the actual price the Provider had paid.
- (j) Each of the DEFENDANTS knew, and in fact, closely monitored the prices, with and without discounts, that Providers as well as wholesalers were paying for DEFENDANTS' specified drugs. Such information was of utmost importance to

DEFENDANTS in conducting their business affairs such as calculating and projecting revenue and profits, and making marketing, manufacturing and distribution decisions.

- (k) Each of the DEFENDANTS had information readily available to them which would have enabled them to report price and cost information which fairly and reasonably represented sales in the marketplace.
- (I) Each of the DEFENDANTS was, at a minimum, generally aware of the size of the "Spread" for their respective specified drugs under both Medicare and Medicaid.
- (m) The DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that the prices they reported to First DataBank, Red Book and Medi-Span were vastly higher than, and bore no relation whatsoever to, the actual prices which Providers were paying for their specified drugs.
- (n) The DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that, all other factors being equal, the greater the "Spread" on a drug, the greater the likelihood a Provider would purchase that drug versus a competing brand or generic drug.
- (o) Each of the DEFENDANTS systematically concealed or otherwise failed to report decreases in the actual prices to the Providers of the specified drugs.
- 150. Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that Federal and State statutes and regulations prohibited them from making misleading representations about the specified drugs, including misleading price or cost representations.

- 151. Each of the DEFENDANT DRUG MANUFACTURERS was required to comply with the Federal Food, Drug and Cosmetic Act 21 U.S.C. §321 et seq., and the regulations promulgated pursuant thereto.
- 152. The price and cost representations about the specified drugs constituted advertising that was included in the "labeling" provisions of the Federal Food and Drug Act and related regulations. 21 U.S.C. §§201(m); 202.1(k)(2).
- 153. Each of the DEFENDANT DRUG MANUFACTURERS is prohibited from disseminating any information about their prices or costs of the specified drugs that was "false or misleading in any particular . . ." 21 U.S.C. §§5.02; 302(b).
- 154. Each of the DEFENDANT DRUG MANUFACTURERS possessed a duty to assure that their representations about prices and costs of the specified drugs were not misleading, taking into account:
 - "... not only representations made or suggested by statement, word, design, device, or any combination thereof, but also to the extent to which the labeling or advertising fails to reveal facts material in light of such representations"

21 U.S.C. §201(n).

- 155. The DEFENDANT DRUG MANUFACTURERS regularly made direct representations of false price and cost information to State Medicaid Programs that were utilized in approving and paying claims.
- 156. The DEFENDANT DRUG MANUFACTURERS were each fully capable of making truthful representations about prices and costs of the specified drugs and did so when it was economically beneficial to them, a fact which further indicates that they acted

with knowledge, as when the DEFENDANTS' supplied drug price reports to the federal government in connection with the Medicaid Rebate Program.

- 157. The DEFENDANT DRUG MANUFACTURERS each participated in the Medicaid Rebate Program (the "Rebate Program") mandated by the Federal Omnibus Budget Reconciliation Act of 1990 ("OBRA '90") and thus were required to pay rebates to State Medicaid Programs. The goal of the Rebate Program was to provide Medicaid with the benefit of the drug manufacturers' best prices. In calculating rebates it was in the economic interests of the DEFENDANT DRUG MANUFACTURERS to report the lowest Average Manufacturers Price ("AMPs") possible based upon the data available to them.
- 158. With respect to the drugs at issue in this case, when reporting prices for reimbursement purposes the DEFENDANT DRUG MANUFACTURERS falsely reported amounts far in excess of those reported for Rebate Program purposes. Therefore, when it benefitted the DEFENDANT DRUG MANUFACTURERS to report high prices in order to maximize the reimbursement amount for Providers, they used the false and grossly inflated prices and, when it benefitted the DEFENDANT DRUG MANUFACTURERS to report their true prices, which were much lower, to minimize the rebates they were required to pay the Rebate Program, they used the true prices.
- 159. The knowledge or gross recklessness of DEFENDANTS is further shown by the Rebate Program because the vast difference between the AMP's being reported for federal rebate purposes and prices and costs being reported for reimbursement purposes made it obvious that the reported reimbursement costs and prices were grossly inflated, yet they were never corrected.

- 160. Each DEFENDANT DRUG MANUFACTURER was on notice that it was prohibited by federal statute from paying, or causing the payment of, directly or indirectly, money or other financial benefit to induce its customers to order the specified drugs when the Medicare or State Medicaid Programs would be paying claims. 42 U.S.C. §1320a-7b(b)(2).
- DEFENDANTS, acting individually and in concert with one another, purposely created confusion and made false and misleading statements about drug pricing in order to deceive the United States Government and the States' Medicaid Programs. For several years, various Governmental agencies including the HHS Office of Inspector General "OIG" and the General Accounting Office "GAO" attempted to examine the issue of the reasonableness of reimbursements by the Medicare and States' Medicaid Programs for many of the drugs at issue in this Fourth Amended Complaint. The OIG's and GAO's efforts were thwarted, in part, by the DEFENDANTS withholding and concealing pertinent information that was being sought by the OIG and GAO. The OIG and GAO attempted through numerous published reports to identify the problem of unreasonable reimbursements; however, they were unsuccessful due to the actions of the DEFENDANTS. The DEFENDANTS concealed and disguised the unreasonable reimbursements from the United States Government and States' Medicaid Programs, in part, by the following facts and circumstances:
- a) The DEFENDANTS can and do make truthful representations of price and costs for many of their drugs sold in retail community pharmacies and, in some

instances, infusion, injectable and inhalation drugs and biologicals sold to physician groups, outpatient clinics and pharmacies.

- b) Some of the DEFENDANTS make representations of cost and price in terms of "List Price," "Wholesale Net," Direct Price "DP" or "DIRP,"or Wholesaler Acquisition Costs, "WAC," to which Medical Economics and First DataBank apply an industry average mark-up and establish an AWP.
- c) Some of the DEFENDANTS make representations of cost and price in terms of both AWP and DP (or DIRP).
- d) All of the DEFENDANTS make or cause to be made falsely inflated price and cost representations of one or more of Wholesale Net Price/WAC, Direct Price and/or AWP that were utilized by the government in calculating and paying drug reimbursements.
- 162. Notwithstanding the DEFENDANTS' knowledge that the Government relied upon the DEFENDANTS' representations of price and cost and their knowledge of the applicable statutory requirements and prohibitions, each of the DEFENDANTS repeatedly, systematically and falsely reported inflated price and cost information, including but not limited to:
- a) Defendants ABBOTT,

 repeatedly, systematically and falsely represented to the Medicare and

 States' Medicaid Programs that the prices of certain of the generic versions of the specified drugs were the same or higher than the published price for the equivalent brand drug when they knew that, in truth and in fact, the price of their generic drug was far less than the

published price of the brand and that the States' Medicaid Programs and Medicare would pay and approve claims based upon their false representations of the price of their drugs, and

Defendants ABBOTT,

b)

- repeatedly, systematically and falsely represented to the Medicare and States' Medicaid Programs that the prices of certain of their specified drugs were increasing or remaining substantially constant when they knew that in truth and in fact the prices had fallen substantially or were otherwise priced far below the represented prices and the Medicare and States' Medicaid Programs would pay and approve claims based on their false representations of the price of their drugs.
- 163. The grossly excessive profits have led to a proliferation of illegal split fee arrangements between the drug manufacturers' customers and persons or entities who are in a position to refer patients. The split fee/kickbacks also serve as a financial inducement for the referrals of more patients and greater utilization of the products.
- 164. In systematic and ongoing written and verbal communications with customers, the DEFENDANTS "marketed the spread" by encouraging and inducing customers to submit claims to Medicare and Medicaid to receive the excessive payments resulting from the DEFENDANTS' false price and cost representations.

SECTION NO. 10

THE DEFENDANTS HAVE REPEATEDLY UNDERMINED THE VARIOUS EFFORTS THAT FEDERAL AND STATE GOVERNMENTS HAVE MADE TO ENSURE THAT GOVERNMENT DRUG REIMBURSEMENT AMOUNTS ARE REASONABLE

- 165. The DEFENDANTS have each knowingly and actively impeded the numerous efforts made by Government to provide for reimbursement of prescription drugs at a reasonable rate.
- Estimate Providers' Drug Costs under Medicare/Medicaid. DEFENDANTS impede such efforts on the part of the Government by means of the knowing reporting of inflated price and cost information alleged throughout this Fourth Amended Complaint and by additional affirmative acts such as those alleged herein.
- Their Efforts To Verify That Drug Manufacturers Provide Good Faith Price And Cost Information For Reimbursement Purposes. By way of example, the Texas Medicaid authorities, during the time at issue in this Fourth Amended Complaint, required each of the DEFENDANTS to certify, in writing, their price and cost representations as a condition to their drugs being covered for reimbursement. The Relator's investigation has revealed that each of the DEFENDANTS, when responding to Texas, either affirmatively lied about their true prices, or omitted material information in order to mislead the Texas Medicaid officials.

168. Had the DEFENDANTS truthfully disclosed the price and cost information about the specified drugs, Texas Medicaid would have set reimbursement amounts for the specified drugs consistent with a reasonable estimation of acquisition cost. Because each of the DEFENDANTS having a duty to make truthful disclosures made false statements or omissions about the specified drugs, Texas Medicaid reimbursement has been paid at substantially greater amounts than intended by applicable law and Texas Medicaid policy.

169. The DEFENDANTS Thwarted Governments' Efforts to Receive the Benefit of Drug Manufacturers' Best Prices under the Medicaid Rebate Program. As previously alleged herein, the DEFENDANTS have each participated in the Rebate Program and as such were required to calculate their drugs BP and/or AMP.

170. If a manufacturer truthfully reports its AMP and WAC they should be very close to, if not the same, amount. However, for reimbursement purposes the DEFENDANTS have in many instances falsely and fraudulently represented inflated (or caused to be inflated) AWP's and WAC's that are in some cases more than 500% over their AMP's. These inflated reported prices and costs virtually nullify the intended effect of the Rebate Program which is to provide the Government with the benefit of the DEFENDANTS' best prices in the market place.

SECTION NO. 11

THE SPECIFIC FALSE PRICE AND COST REPRESENTATIONS OF DEFENDANT ABBOTT

171. Throughout the period starting from on or before December 31, 1993 and continuing through the first quarter of 2001, Defendant ABBOTT knowingly caused

Medicare/Medicaid to pay false or fraudulent claims for prescription drugs and/or biologicals (collectively referred to in this Section as the "drugs") including those specified in this Section, and further made or used false or fraudulent records and/or statements to get such claims paid or approved. As a result of the said actions of Defendant ABBOTT and those persons and entities acting directly or indirectly in concert with Defendant ABBOTT, Medicare/Medicaid paid grossly excessive, unreasonable and unlawful amounts for claims for the drugs, including those specified in this Section. The acts committed by Defendant ABBOTT that caused Medicare/Medicaid to pay or approve said false or fraudulent claims included, but were not necessarily limited to, knowingly making false or fraudulent representations about prices and costs of the drugs which Defendant ABBOTT knew would be utilized by Medicare/Medicaid in paying or approving claims for such drugs and using the Spread as a financial inducement to increase sales of the Defendants' drugs. Each of said representations was in fact utilized by Medicare/Medicaid in paying or approving claims for such drugs.

172. Defendant ABBOTT knowingly caused its false or fraudulent price and cost representations to be published in the years specified in this Section in the Red Book, the Blue Book, First DataBank's Automated Services and Medi-Span and further made or used false records or statements regarding its prices and costs of drugs, including those specified in this Section, and submitted same to Medicare/Medicaid continuously throughout the years specified in this Section. By way of example, the said false price and cost representations as they were reported by Defendant ABBOTT and reflected in Red Book, Blue Book, First DataBank and the inflated Medicaid reimbursement amounts

calculated by Florida and Texas have been organized into a chart form for certain of the drugs in question. Amounts contained in the Florida Medicaid reimbursement column reflect the falsely inflated reported First DataBank WAC costs because Florida's reimbursement methodology for the years listed in each chart was WAC (as reported in First DataBank) plus 7%. Amounts contained in the Texas DEAC (Direct Estimated Acquisition Cost) reimbursement column also reflect the fact that the Defendant's price and cost representations were falsely inflated as explained more fully in ¶ 110, herein. The amount listed under the Relator's Cost column reflects the actual prices that were available to the Relator for the listed drugs from ABBOTT or a wholesaler. As a very small infusion pharmacy, the Relator did not always receive the lowest prices available to volume purchasers. Accordingly, in many instances the actual cost to Providers for the drug was significantly lower than that paid by the Relator. In instances where a given Provider did pay less for a drug than did the Relator, the Spread on said drug would have been correspondingly greater than that received by the Relator. A listing of drugs with respect to which ABBOTT knowingly caused Medicare/Medicaid to pay falsely inflated reimbursement amounts by reporting falsely inflated drug costs and prices is contained in Exhibit 6 attached hereto.

				DEFENDANT	ABBOTT			
				्रेन्द्रकारमा १० १९५४ - मानुस्य १९५४ - स्टब्स्ट्र	enger Selfore			
Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated System	Texas 'DEAC" Medicaid Relmburse- ment Based On False Reported Prices	Florida Medicaid Reimburse- ment Based On False Reported "WAC"	Relator's Cost
1993	\$8.59	\$ 8.59		\$7.23			\$8.03	\$1.07
1994	\$9.01	\$ 9.01	\$14.65	\$7.59	\$11.28		\$8.28	\$0.95
1995	\$9.29	\$ 9.29	\$13.93	\$7.82	\$11.73		\$8.51	\$0.95
1996	\$9.56	\$ 9.56	\$ 14.63	\$8.05	\$12.33		\$8.92	\$0.95
1997	\$1 0.03		\$ 15. 3 8		\$12.95	\$8.87	\$9.37	\$0.95
1998	\$ 10.53		\$11.05		\$9.30		\$9.37	\$1.33
1999	\$11.06		\$ 12.06					\$ 1.60
2000	\$11.61							\$ 1.65
2001	\$11.61							\$1.65
				हार विकास स्थाप स्थाप स्थाप	ine opa ix			
Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated System	Texas "DEAC" Medicaid Reimburse- ment Based On False Reported Prices	Florida Medicaid Relmburse- ment Based On False Reported "WAC"	Relator's Cost
1993	\$8.72	\$8.72		\$ 7.34			\$8.15	\$0.97
1994	\$9.16	\$9.16	\$10.00	\$7.71	\$8.40		\$8.40	\$0.96
1995	\$9.43	\$9.43	\$10.25	\$ 7.94	\$8.65		\$8.64	\$0.96
1996	\$9.71	\$9.71	\$10.80	\$8.18	\$ 9.10		\$9.08	\$0.96
1997	\$10.20		\$11.30		\$9.55		\$9.53	\$0.96

				DEFENDAN	T ABBOTT			
1998	\$10.71		\$11.25		\$9.45		\$ 9.53	\$1.50
1999	\$ 11.25							\$1.46
2000	\$11.80							\$1 .07
2001	\$11.80			:				\$1.07
			V Yes	126 (1997) 126 (1997) 126 (1997)	FIXEN OF ST	ra (
Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated System	Texas 'DEAC" Medicald Reimburse- ment Based On False Reported Prices	Florida Medicaid Reimburse- ment Based On False Reported "WAC"	Relator's Cost
1993	\$ 9.37	\$ 9.37		\$ 7.89			\$8.75	\$1.04
1994	\$9.83	\$9.83	\$10.15	\$8.28	\$8.55		\$9.00	\$1.03
1995	\$ 10.13	\$10.13	\$10.45	\$8.53	\$8.80		\$9.29	\$1.03
1996	\$ 10.44	\$10.44	\$10.95	\$8.79	\$9.25		\$9.75	\$1.03
1997	\$10.96		\$11.50		\$9.70		\$10.24	\$1.03
1998	\$10.96		\$12.10		\$10.15			\$2.00
1999	\$12.08							\$1.61
2000	\$12.68							\$1.15
2001	\$ 12.68							\$1.15
				**************************************	Tin Control			

				DEFENDAN1	ABBOTT			
Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated System	Texas 'DEAC" Medicaid Reimburse- ment Based On False Reported Prices	Florida Medicald Reimburse- ment Based On False Reported "WAC"	Relator's Cost
1993		\$11.64		\$9.81			\$ 10.90	\$1.30
1994	\$12.23	\$12.23	\$22.40	\$ 10.30	\$18.90		\$11.20	\$1,14
1995	\$12.60	\$ 12.59	\$ 13.00	\$10.61	\$10.90		\$ 11.54	\$1,14
1996	\$12.98	\$ 12.97	\$ 13.60	\$10.93	\$11.50		\$12.13	\$1.14
1997	\$13.63		\$14.30		\$12.10		\$12.72	\$1.14
1998	\$14.31		\$ 15.00		\$12.70		\$12.72	
1999	\$15.02							
2000	\$15.77							\$1.26
2001	\$15.77							\$1.26
				ेशानसम्बद्धाः पुराद्वाः १६६२ महास् १६६८ स	TION F REPORT			
Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated System	Texas 'DEAC" Medicald Reimburse- ment Based On False Reported Prices	Florida Medicaid Reimburse- ment Based On False Reported "WAC"	Relator's Cost
1993	\$27,95	\$27.95		\$23.54				\$3.76
1994	\$29.35	\$29.36	\$30.23	\$24.72	\$25.46			\$ 3.51
1995	\$30.23	\$29.36	\$31.45	\$25.46	\$26.48			\$3.51
1996	\$31.44	\$31.45	\$31.45	\$26.48	\$27.80		\$ 30.85	\$ 3.51
1997	\$33.01		\$ 31.45		\$29.19	\$29.19		\$ 3.51
1998	\$34.66		\$36.40		\$30.65			\$3.51
	600.40		1	1	-		1	52.02
1999	\$36.40	<u> </u>	<u> </u>	 	<u> </u>	 		\$3.92

Civil Action No: 95-1354-CIV-GOLD

DEFENDANT ABBOTT								
2001	\$38.21			देशकार संदेशका विकास				\$2.98
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Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated System	Texas 'DEAC" Medicaid Reimburse- ment Based On False Reported Prices	Florida Medicaid Reimburse- ment Based On False Reported "WAC"	Relator's Cost
1993	\$8.74	\$8.74		\$7.36			\$8.17	\$4.92
1994	\$9.18	\$9.18		\$7.73	\$7.96		\$8.42	\$3.63
1995	\$ 9.45	\$9.45		\$ 7.96	\$8.28		\$8.75	\$3.63
1996	\$9.83	\$9.83		\$8.28	\$8.69		\$9.18	\$3.63
1997	\$10.32		\$ 10.83		\$9.12		\$9.64	\$3.63
1998	\$10.83		\$11.38		\$9.58		\$9.68	
1999	\$11.38	ļ ·						
2000	\$11.95							\$3.46
2001	\$ 11.95							\$3.46

				DEFENDAN	T ABBOTT			
Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated System	Texas 'DEAC" Medicaid Relmburse- ment Based On False Reported Prices	Florida Medicald Reimburse- ment Based On Faise Reported "WAC"	Relator's Cost
1993	\$85.00	\$100.94		\$85.00				\$75.00
1994	\$105.98	\$105.98		\$89.25	\$91.93			
1995	\$109.17	\$109.17		\$ 91.93	\$95.61			\$43.00
1996	\$113.54	\$113.54		\$95.61	\$100.39		\$111.40	\$43.00
1997	\$119.21		\$125.17		\$105.41			
1998	\$125.17		\$131.43		\$110.68			
1999	\$131.43							
2000	\$138.00							\$23.38
2001	\$138.00							\$23.38
	fine of the feet of the second			allighters of	भित्तीन जिल्ला			
Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	Faise "AWP" Reported To CA Through FDB Automated	False Direct Price Reported Through FDB Blue Book	iifi Kengapanis	Texas 'DEAC" Medicaid Reimburse- ment Based On False	Florida Medicaid Reimburse- ment Based On False Reported "WAC"	Relator's Cost
	"AWP" Reported Through Red Book	"AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through	'DEAC" Medicaid Reimburse- ment Based On	Medicaid Reimburse- ment Based On False Reported "WAC"	
1993	"AWP" Reported Through Red Book	"AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated	'DEAC" Medicald Reimburse- ment Based On False Reported	Medicaid Reimburse- ment Based On False Reported "WAC"	\$7.25
1993 1994	"AWP" Reported Through Red Book \$23.32	"AWP" Reported Through FDB Blue Book \$23.32	False "AWP" Reported To CA Through FDB Automated	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated	'DEAC" Medicald Reimburse- ment Based On False Reported	Medicaid Reimburse- ment Based On False Reported "WAC" \$21.79	\$7.25 \$3.20
1993 1994 1995	"AWP" Reported Through Red Book \$23.32 \$24.49 \$25.22	"AWP" Reported Through FDB Blue Book \$23.32 \$24.49 \$25.22	False "AWP" Reported To CA Through FDB Automated	False Direct Price Reported Through FDB Blue Book \$19.64 \$20.62	False Direct Price Reported To California Through FDB Automated	'DEAC" Medicald Reimburse- ment Based On False Reported	Medicaid Reimburse- ment Based On False Reported "WAC" \$21.79 \$22.45 \$23.33	\$7.25 \$3.20 \$3.20
1993 1994 1995 1996	"AWP" Reported Through Red Book \$23.32 \$24.49 \$25.22 \$26.23	"AWP" Reported Through FDB Blue Book \$23.32	False "AWP" Reported To CA Through FDB Automated	False Direct Price Reported Through FDB Blue Book	False Direct Price Reported To California Through FDB Automated	'DEAC" Medicald Reimburse- ment Based On False Reported	Medicaid Reimburse- ment Based On False Reported "WAC" \$21.79 \$22.45 \$23.33 \$24.51	\$7.25 \$3.20 \$3.20
1993 1994 1995 1996 1997	"AWP" Reported Through Red Book \$23.32 \$24.49 \$25.22 \$26.23 \$27.54	"AWP" Reported Through FDB Blue Book \$23.32 \$24.49 \$25.22	False "AWP" Reported To CA Through FDB Automated	False Direct Price Reported Through FDB Blue Book \$19.64 \$20.62	False Direct Price Reported To California Through FDB Automated	'DEAC" Medicald Reimburse- ment Based On False Reported	Medicaid Reimburse- ment Based On False Reported "WAC" \$21.79 \$22.45 \$23.33 \$24.51 \$26.96	\$7.25 \$3.20 \$3.20
1993 1994 1995 1996	"AWP" Reported Through Red Book \$23.32 \$24.49 \$25.22 \$26.23	"AWP" Reported Through FDB Blue Book \$23.32 \$24.49 \$25.22	False "AWP" Reported To CA Through FDB Automated	False Direct Price Reported Through FDB Blue Book \$19.64 \$20.62	False Direct Price Reported To California Through FDB Automated	'DEAC" Medicald Reimburse- ment Based On False Reported	Medicaid Reimburse- ment Based On False Reported "WAC" \$21.79 \$22.45 \$23.33 \$24.51	\$7.25 \$3.20 \$3.20
1993 1994 1995 1996	"AWP" Reported Through Red Book \$23.32 \$24.49 \$25.22 \$26.23 \$27.54	"AWP" Reported Through FDB Blue Book \$23.32 \$24.49 \$25.22	False "AWP" Reported To CA Through FDB Automated	False Direct Price Reported Through FDB Blue Book \$19.64 \$20.62	False Direct Price Reported To California Through FDB Automated	'DEAC" Medicald Reimburse- ment Based On False Reported	Medicaid Reimburse- ment Based On False Reported "WAC" \$21.79 \$22.45 \$23.33 \$24.51 \$26.96	\$7.25 \$3.20 \$3.20

			DEFENDANT	T ABBOTT		
2001	\$ 33.40					

As a direct and proximate result of the actions of the Defendant ABBOTT alleged herein, the United States has sustained damages recoverable under the False Claims Act, together with triple damages, penalties, attorneys' fees and costs.

SECTION NO. 12

THE SPECIFIC FALSE PRICE AND COST REPRESENTATIONS OF DEFENDANT

173.		· · · · · · · · · · · · · · · · · · ·			
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PAGES 86 THROUGH 160 HAVE BEEN COMPLETELY REDACTED WHICH INCLUDES PARAGRAPHS 174 THROUGH 217

Civil Action No: 95-1354-CIV-GOLD
COUNT I
FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS
218. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-
CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants:
ABBOTT LABORATORIES, INC.;

, under the False Claims Act, 31 U.S.C.

§§3729-3732.

219. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully

set forth herein and further alleges as follows:

220. The DEFENDANTS, from the dates specified in Sections 11 through 33, to the

present date (except as to ABBOTT for which the period extends to first quarter of 2001) knowingly

[as defined in 31 USC, §3729(b)] caused to be presented to officers or employees of the UNITED

STATES GOVERNMENT and STATE GOVERNMENTS false or fraudulent claims for payment or

approval, in that the DEFENDANTS caused to be presented to officers or employees of the

UNITED STATES GOVERNMENT and STATE GOVERNMENTS false or fraudulent price and cost

information for the specified drugs (as the term "specified drugs" has been defined throughout the

Complaint) and caused the UNITED STATES and STATE GOVERNMENTS to pay out sums of

money to the Providers and suppliers of the DEFENDANTS' specified drugs, grossly in excess of

the amounts permitted by law, resulting in great financial loss to the UNITED STATES and STATE

GOVERNMENTS.

221. Because of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' conduct

as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion

Dollars (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(1)

COUNT II

FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED TO GET A FALSE OR FRAUDULENT

CLAIM PAID OR APPROVED BY THE GOVERNMENT

222. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-

CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants:

162

, under the False Claims Act, 31 U.S.C. §§3729-3732.

- 223. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows:
- 224. The DEFENDANTS, from the dates specified in Sections 11 through 33, to the present date (except as to ABBOTT for which the period extends to the first quarter of 2001) knowingly [as defined in §3729(b)] caused false records or statements to be made or used to get false or fraudulent claims to be paid or approved by the GOVERNMENT, in that the DEFENDANTS, caused false records or statements of prices and costs of the DEFENDANTS' drugs specified herein to be used by the GOVERNMENT to pay or approve claims presented by the Providers and suppliers of the DEFENDANTS' specified drugs, which claims were grossly

in excess of the amounts permitted by law, resulting in great financial loss to the UNITED STATES and STATE GOVERNMENTS.

225. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(2).

COUNT III

FALSE CLAIMS ACT; CAUSING FALSE RECORDS OR STATEMENTS TO BE USED TO CONCEAL AN OBLIGATION TO PAY MONEY TO THE GOVERNMENT

	226.	Inis is a	civil acti	ion by th	e Plaintii	ff, UNITE	D STATE	S, and the	ne Rela	tor, VE	V-A-
CARE,	on bel	half of the	UNITED	STATE	S and on	behalf o	f the Rela	itor, agair	nst the l	Defenda	ants:
ABBO [*]	TT LAE	BORATO	RIES, IN	C.;							
								-			
					•						

, under the False Claims Act, 31 U.S.C.

§§3729-3732.

227. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows:

228. The DEFENDANTS, from on or before the dates specified in Sections 11 through 33, to the present date (except as to ABBOTT for which the period extends to first quarter of 2001) knowingly (as defined in §3729(b)) caused false records or statements to be made or used to conceal obligations to pay money to the GOVERNMENT, in that: the DEFENDANTS knew that the UNITED STATES' Medicare Program and the States' Medicaid Programs had used the DEFENDANTS' false price and cost representations for purposes of paying or approving claims of the Providers and suppliers of the DEFENDANTS' specified drugs; the DEFENDANTS knew that sums of money paid by the UNITED STATES and States' Governments to the Providers and suppliers of the DEFENDANTS' specified drugs were grossly in excess of the amounts permitted by law; the DEFENDANTS knew it was the obligation of the UNITED STATES Medicare Part B carriers and State Governments to recoup governments' funds paid in excess of the amounts permitted by law; the DEFENDANTS, nevertheless, continued to conceal the fact that they had caused to be made or used false records or statements of prices and costs for the specified drugs that were grossly in excess of the reasonable amounts permitted by law and to conceal from the GOVERNMENT an obligation to pay to the GOVERNMENT the excessive reimbursement amounts

229. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(7).

paid to Providers for which DEFENDANTS were directly responsible.

COUNT IV

FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS; ILLEGAL REMUNERATION

	230.	This is	a civil act	ion by the	Plaintiff,	UNITED	STATES,	and the F	Relator, VE	N-A-
CARE	, on be	half of the	UNITEC	STATES	and on b	ehalf of th	e Relator	, against t	he Defend	lants:
ABBO	TT LA	BORATO	RIES, IN	C.;						
					, under	he False (Claims Ac	t, 31 U.S.(C. §§3729	-3732.

- 231. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows:
- 232. The DEFENDANTS, from the dates specified in Sections 11 through 33, to the present date (except as to ABBOTT for which the period extends to first quarter of 2001) knew

that the prices charged to their customers for the specified drugs were significantly reduced in amount from the prices and costs represented by the DEFENDANTS and upon which the DEFENDANTS knew Medicare and Medicaid claims would be approved and paid. Accordingly, the DEFENDANTS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from the Medicare and/or States' Medicaid Programs to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified drugs for which the DEFENDANTS knew that payment would be made, in whole or in part, by the Medicare and States' Medicaid Programs. Such financial inducement is specifically prohibited by 42 U.S.C. §1320a-7b(b) and 18 U.S.C §2.

- 233. The DEFENDANTS' knowing and willful actions in arranging for their customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b), in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused the claims for the specified drugs to be false and fraudulent claims and caused the claims to be presented to the Medicare and States' Medicaid Programs for payment and approval in violation of 31 U.S.C §3729(a)(1).
- 234. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00) all in violation of 31 U.S.C. §3729(a)(1).

COUNT V

FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR
STATEMENT TO BE MADE OR USED TO GET
A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE
GOVERNMENT; PROHIBITED REFERRALS,
CLAIMS AND COMPENSATION ARRANGEMENTS

235.	This is a civil action by the	Plainuii, UNITED STATE	5, and the Relator, VEN	i-A-
CARE, on be	half of the UNITED STATES	and on behalf of the Relat	or, against the Defendar	nts:
ABBOTT LA	BORATORIES, INC.;			
				_
		·		
			·	
		under the False Claims	Act. 31 U.S.C. §§3729-3	732.

236. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows:

- 237. The DEFENDANTS, from the dates specified in Sections 11 through 33 to the present date (except as to ABBOTT for which the period extends to first quarter of 2001) knowingly presented or caused to be presented, prohibited claims or bills to individuals and other entities for designated health services [outpatient prescription drugs] furnished pursuant to prohibited referrals from physicians, physician groups and/or outpatient clinics with which the DEFENDANTS had financial relationships, for which the DEFENDANTS knew that payment would be made, in whole or in part, by the Medicare and/or States' Medicaid Programs. Such prohibited referrals, claims, bills and compensation arrangements are specifically prohibited by 42 U.S.C. §1395nn(a)(1)(B) and 18 U.S.C §2.
- 238. The DEFENDANTS knowingly made or used or caused their referring physicians, physician groups or outpatient clinics to make or use false records or statements to get false or fraudulent claims and bills for the DEFENDANTS' outpatient prescription drugs to be paid or approved by the Medicare and/or States' Medicaid Programs.
- 239. The DEFENDANTS' knowing presentment or causing others to present, claims or bills to the Medicare and/or States' Medicaid Programs in violation of 42 U.S.C. §1395nn(a)(1)(B) without disclosing facts revealing said violations constituted the making or using, or the causing others to make or use, false records or statements to get a false or fraudulent claims paid or approved by the GOVERNMENT in violation of 31 U.S.C. §3729(a)(2).
- 240. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00) all in violation of 31 U.S.C. §3729(a)(2).

COUNT VI

FALSE CLAIMS ACT; CONSPIRING TO DEFRAUD THE GOVERNMENT BY GETTING A FALSE OR FRAUDULENT **CLAIM ALLOWED OR PAID**

	241.	This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-
CARE,	, on bel	naif of the UNITED STATES and on behalf of the Relator, against the Defendants:
ABBO	TT LAE	BORATORIES, INC.;
		· ·
		, under the False Claims Act, 31 U.S.C. §§3729-3732
	242.	Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully

- set forth herein and further alleges as follows.
- 243. This Count pertains to all DEFENDANTS manufacturing specified drugs which were multiple-source drugs subject to the "J Code" Medicare reimbursement methodology described

herein (for purposes of this Count each such drug is hereinafter referred to as "a J Code drug"). Each DEFENDANT which reported a falsely inflated AWP for a J Code drug is jointly and severally liable along with all other DEFENDANTS who reported a falsely inflated AWP for a J Code drug falling under the same HCPCS code for the sum of all falsely inflated reimbursement amounts under said HCPCS code in that they conspired to defraud the Government by getting a false claim paid or approved by Medicare via the submission of false or fraudulent price information for the inflated J Code drugs, which jointly caused the UNITED STATES to pay out sums of money to the Providers of the DEFENDANTS' J Code drugs which were grossly in excess of the amounts permitted by law, resulting in great financial loss to the UNITED STATES.

- 244. With respect to State Medicaid Programs, this Count also applies to all DEFENDANTS manufacturing specified drugs which: 1) were multiple-source drugs, 2) were subject to a State Medicaid reimbursement methodology similar to the Medicare "J Code" methodology described herein, and 3) had a falsely inflated reported AWP or another falsely inflated reported price or cost if such price or cost was utilized in creating an array of prices or costs from which one was selected for reimbursement of all versions of a given drug.
- 245. Each DEFENDANT'S liability as to this Count extends from the time it first reported a falsely inflated AWP, or in the case of Medicaid, a falsely inflated AWP or such other price or cost used to create the array of drug prices or costs, until such time, if any, each DEFENDANT stopped reporting said inflated AWP or, in the case of Medicaid, stopped reporting said inflated AWP or such other reported price or cost used to create the array of drug prices or costs from which one was selected for reimbursement purposes.
- 246. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Million Dollars (\$1,000,000), all in violation of 31 U.S.C. §3729(a)(3).

REQUESTS FOR RELIEF

WHEREFORE, the Relator, on behalf of the UNITED STATES, demands that judgment
be entered in its favor and against Defendants: ABBOTT LABORATORIES, INC.;
, with judgment to be entered against each DEFENDANT for the amount of
damages: (1) to the States' Medicaid Programs arising (a) from claims for each
DEFENDANT'S respective specified drugs and (b) jointly and severally with such other
Defendants for damages as set forth in paragraphs 121 and paragraphs 241-246 herein

and (2) to the Medicare Program arising from claims for those drugs classified under the HCPCS codes covering their specified drugs, and jointly and severally with such other Defendants whose drugs fall under said HCPCS codes, as follows:

- 1. On Count I (False Claims Act; Causing Presentation of False Claims) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false claim;
- 2. On Count II (False Claims Act; Causing False Statements To Be Used To Get False Claims Paid Or Approved By The GOVERNMENT) for triple the amount of UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement;
- 3. On Count III (False Claims Act; Causing False Statements To Be Used To Conceal An Obligation To Pay Money To The GOVERNMENT) for triple the amount of the UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false or fraudulent claim paid;
- 4. On Count IV (False Claims Act; Causing Presentation of False and Fraudulent Claims; Illegal Remuneration) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false claim;
- 5. On Count V (False Claims Act; Causing a False Record or Statement to be Made or Used to get a False or Fraudulent Claim Paid or Approved by the Government; Prohibited Referrals, Claims and Compensation Arrangements) for triple the amount of the UNITED

STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement:

6. On Count VI (False Claims Act; Conspiring To Defraud The Government By Getting A False Or Fraudulent Claim Allowed Or Paid) for triple the amount of the UNITED STATES' and States' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false record or statement.

Further, the Relator, on its behalf, requests that it receive the maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the UNITED STATES, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. The Relator requests that its award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Respectfully submitted,

James J. Breen

Florida Bar No. 297178

Alison Simon

Florida Bar No. 0109568

THE BREEN LAW FIRM, P.A.

P. O. Box 297470

Pembroke Pines, FL 33029

Telephone: 954-499-1171

Facsimile: 954-499-1173

Sherrie R. Savett
Gary L. Azorsky
Susan S. Thomas
Jeanne A. Markey
Joy Clairmont
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Telephone: 215-875-3000

CERTIFICATE OF SERVICE

Respectfully submitted,

James J. Breen

Florida Bar No. 297178

Alison W. Simon

Florida Bar No. 0109568

THE BREEN LAW FIRM, P.A.

P.O. Box 297470

Pembroke, Pines, FL 33029

Telephone: 954-499-1171

Case No: 95-1354-CIV-GOLD

EXHIBIT "1"

INT BY: VENACARE;

filliam R. Archer III, M.D.

ommissioner of Health

3052921739;

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PAGE 3

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TDH

Texas Department of Health

http://www.tdhistate.pe.us

1100 West 49th Street Austin, Texas 78756-3199 (512) 458-7111 Patti J. Patterson, M.D., M.P.H. Executive Deputy Commissioner

Inder the Omnibus Budget Reconciliation Act (OBRA) of 1990, the state of Texas Vendor Drug Program vill continue to request completed questionnaire as a requirement for the production addition to the Texas 'endor Drug Index (TVDI). A form is included so that all necessary information from the manufacturer will envailable for pricing and dosing recommendations. Questionnaires should be limited to no more than 20 er submittal request for any one month period. A separate questionnaire is to be submitted for each drug and strength. Please supply a cover sheet listing all products, strengths and package sizes for which you are ubmitting: Dications. Questions must be answered in full MO-NA. This form may be reproduced.

all inquiries regarding this questionnaire for BYD and revisions are to be directed to:

Texas Department of Health BureauVendor Drug 1100 West 49th Street. Austin, Texas 78756-3174

Drugs are listed in the BVD using the NDC number of the manufacturer or distributor who is holding the drug forth as his own and has his company's name on the label of the container that is sold to the pharmacy. If your company has a product to which the "New Drug Coverage" applies, please add the FDA approval date of the New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA), or Antibiotic Drug Approval (ADA) to the questionnaire.

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug
(512)338-6965
(512)338-6462-Fux
(512)338-6932-Secretary

EXHIBIT "1"

An Equal Employment Opportunity Employer

NT BY: VENACARE;		3052921739;	JAN-16 '	7:25PM;	PAGE 4
מוי אכוויאירטאתבי		TOUR SEATON	ALTERNATION	ومعيد فعلك	* man
REQUEST ADDI	LIONAL	FORMA'IION FOR NEW INFORMATION OF PR NCLUDED IN TEXAS M	ODUCTS CURRENT	OR FOR ILY	· .
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LUDE A COPY OF FIL	CARD	, PACKAGE INSERT A	ND OR MATERIA	L FOR PHYSI	CIANS
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C. NO:		PACKAGE QTY:		V	
altiple package size of same sue	ngth	products may be included)		a, f	
ODUCT BRAND NAME: NERIC NAME: STRUCTURALLY RELA		UGS;			-
.UG STRENGTH:					
LOR:		FLAVOR:	ORANGE BOOK	rating:	
SAGE FORM:		IS THIS DRUG LEGEND OR OTC?	DEA SCHEDULI DRUG:	OF THE	
XIMUM DAILY DOSE:					
OMMENDED DAILY I	OSE:				
GREDIENTS/DESCRIPT	ON:				
LIST SHELF LIFE:			·		
ESTIMATED AVG. DUR	MOITA	of therapy:			
MAXIMUM DURATION	OF TRI	ATMENT:			
A - Drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products. B - Drug products that FDA at this time, considers not to be therapeutically equivalent to					
B - Drug proc other pha	maceuil	FDA at this time, considerably equivalent products	ra not to oc merapeut	neatty editivation	. 10
C - Not listed					
** NEW ADDITION	AL INF	ORMATION - revised (April 1, 1998)		•
		the the terms	u la Caralau u		า

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grant control		·	-	a a Marina dan	
CH COPIES OF PR	ice list & ADD to mailing list if	NOT CUI	rrently	LISTED**	
	PRICE INFORMATION		•·	•••	
erage of suggested	WHOLESALE PRICE TO PHARMACY (A	.WP)	S		7
ce to wholesaler a	ND/OR DISTRIBUTOR		\$		
ECT PRICE TO PHARM	ACY		\$		
CE TO CHAIN WAREHO	USE		S		
VSTITUTIONAL OR OTE ursing Home, Home Healt	IER CONTRACT PRICE**		2		
HER PRICE			S		
stes: If prices yary by spe	ent for multiple submittals. cific contract or customer Arrangement, you whom you report pricing information.	u may pro	yid e a pric	erango.**	•
ST DATA BANK PRICE A	LERT RED BOO	K			
NA92-IC	BLUEBO	OOK			
R:					
lo you sell to distributors, r ell your product to the retal	cpackagers, or relablers, other than full-service trade bearing your NDC number?	e drug wh	olesalers,	who in turn	
f yes, attach a listing.	· ·			•	
	agreement with retail pharmacists (contract, p	oolicy, etc)		. :	
Attach a copy of your Vend	for Liability Insurance:				
i. Included or					
a. Previously submitted or	unchanged. (Do not need to resubmit)			.:	
Available date through WF	HOLESALERS				-
	An Equal Employment Opportunity Employe	er			3

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Dr. 42111A UAILE	· ·		* ~	AND THE PROPERTY OF THE PROPER	•
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e of firm:				** ***	
ress:				•	
	State:		Zip:		
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ne and Address of represent	tatives/governi	nent affairs persons co	vering the Texas ar	ca; if applicable	· <u></u>
	Sune:		Zip:		· · · · · · · · · · · · · · · · · · ·
nc:					- 1
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his product now marketer	l under an appr	roved NDA or ANDA?			
ubmit a copy of the FDA letter of approval for market	tter of approva			ble, a copy of th	FDA
,	J				:
lease circle DESI classific	ation of this pro	oduct.			:
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and added to the Texas Ver	ndor Drug Program	must bear the labo	eler code, as define	d by the FDA, o	fthe.
with the exception of a bon	iathre imi-sciaice di	ng wholesaler, ma	arketing the linal s	ile to the provide	I.
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acturers or distributors have mitting notification of any reduled to occur to:	ring one or more of a changes pertaining	their pharmaceusic to any of the abov	eals included in the e information not	program are res later than such re	ponsible visions
	Texas De	partment of Healt	ĥ		
	Bureau	of Vendor Drug			
		rtha McNeill, R.P. Product Managen		<u></u> . •	
		Product Managen West 49th Street	icii		
		Texas 78756-3174	1		
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y that the information sub- on of either Federal or State	mined is correct to t te Law. I also agree	ne best of my kno to inform the Tex	wicage and that in (as Department of)	is product is not Health. In writing	now in z. of anv
s in formulation, product	status, price or avail	ability as herein d	escribe, within fift	een (15) days of	such
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nsible Person (Type or Pri	nt)		Signature		•
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Case No: 95-1354-CIV-GOLD

EXHIBIT "2"